## S. 2565

To amend the Federal Food, Drug, and Cosmetic Act to clarify the circumstances in which a substance is considered to be a pesticide chemical for purposes of such Act, and for other purposes.

## IN THE SENATE OF THE UNITED STATES

OCTOBER 7 (legislative day, OCTOBER 2), 1998

Mr. Durbin (for himself, Mr. Warner, Ms. Mikulski, Mr. Hutchinson, Mr. Robb, Mr. Kennedy, and Mr. DeWine) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to clarify the circumstances in which a substance is considered to be a pesticide chemical for purposes of such Act, and for other purposes.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "Antimicrobial Regula-
- 5 tion Technical Corrections Act of 1998".

1	SEC. 2. DEFINITION OF PESTICIDE CHEMICAL UNDER FED-
2	ERAL FOOD, DRUG, AND COSMETIC ACT.
3	(a) In General.—Section 201(q) of the Federal
4	Food, Drug, and Cosmetic Act (21 U.S.C. 321(q)) is
5	amended by striking " $(q)(1)$ " and all that follows through
6	the end of subparagraph $(1)$ and inserting the following:
7	" $(q)(1)(A)$ Except as provided in clause (B), the term
8	'pesticide chemical' means any substance that is a pes-
9	ticide within the meaning of the Federal Insecticide, Fun-
10	gicide, and Rodenticide Act, including all active and inert
11	ingredients of such pesticide. Notwithstanding any other
12	provision of law, the term 'pesticide' within such meaning
13	includes ethylene oxide and propylene oxide when such
14	substances are applied on food.
15	"(B) In the case of the use, with respect to food, of
16	a substance described in clause (A) to prevent, destroy,
17	repel, or mitigate microorganisms (including bacteria, vi-
18	ruses, fungi, protozoa, algae, and slime), the following ap-
19	plies for purposes of clause (A):
20	"(i) The definition in such clause for the term
21	'pesticide chemical' does not include the substance if
22	the substance is applied for such use on food, or the
23	substance is included for such use in water that
24	comes into contact with the food, in the preparing,
25	packing, or holding of the food for commercial pur-

poses. The substance is not excluded under this sub-

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clause from such definition if the substance is ethylene oxide or propylene oxide, and is applied for such
use on food. The substance is not so excluded if the
substance is applied for such use on a raw agricultural commodity, or the substance is included for
such use in water that comes into contact with the
commodity, as follows:

"(I) The substance is applied in the field.

"(II) The substance is applied at a treatment facility where raw agricultural commodities are the only food treated, and the treatment is in a manner that does not change the status of the food as a raw agricultural commodity (including treatment through washing, waxing, fumigating, and packing such commodities in such manner).

"(III) The substance is applied during the transportation of such commodity between the field and such a treatment facility.

"(ii) The definition in such clause for the term 'pesticide chemical' does not include the substance if the substance is a food contact substance as defined in section 409(h)(6), and any of the following circumstances exist: The substance is included for such use in an object that has a food contact surface but

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1 is not intended to have an ongoing effect on any por-2 tion of the object; the substance is included for such 3 use in an object that has a food contact surface and is intended to have an ongoing effect on a portion 5 of the object but not on the food contact surface; or 6 the substance is included for such use in or is ap-7 plied for such use on food packaging (without regard 8 to whether the substance is intended to have an on-9 going effect on any portion of the packaging). The 10 food contact substance is not excluded under this 11 subclause from such definition if any of the following 12 circumstances exist: The substance is applied for 13 such use on a semipermanent or permanent food 14 contact surface (other than being applied on food 15 packaging); or the substance is included for such use 16 in an object that has a semipermanent or permanent 17 food contact surface (other than being included in 18 food packaging) and the substance is intended to 19 have an ongoing effect on the food contact surface. With respect to the definition of the term 'pesticide' that 20 21 is applicable to the Federal Insecticide, Fungicide, and Rodenticide Act, this clause does not exclude any sub-23 stance from such definition.".

(b) REGULATIONS.—Section 408(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(j)) is amended by adding at the end the following paragraph: "(4) CERTAIN SUBSTANCES.—With respect to a substance that is not included in the definition of the term 'pesticide chemical' under section 201(q)(1) but was so included on the day before the date of the enactment of the Antimicrobial Regulation Tech-nical Corrections Act of 1998, the following applies as of such date of enactment:

- "(A) Notwithstanding paragraph (2), any regulation applying to the use of the substance that was in effect on the day before such date, and was on such day deemed in such paragraph to have been issued under this section, shall be considered to have been issued under section 409.
- "(B) Notwithstanding paragraph (3), any regulation applying to the use of the substance that was in effect on such day and was issued under this section (including any such regulation issued before the date of the enactment of the Food Quality Protection Act of 1996) is deemed to have been issued under section 409.".

- 1 (c) Technical Amendment.—Section 201(q)(3) of
- 2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
- 3 321(q)(3)) is amended in the matter preceding clause (A)
- 4 by striking "paragraphs (1) and (2)" and inserting "sub-

5 paragraphs (1) and (2)".

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